IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Applicant: Walker	)	Art Unit: 3763
Serial No.: 09/939,239	)	Examiner: Desanto
Filed: August 24, 2001	)	**001/017 (1-3) USA**
	)	November 8, 2004
	)	750 B STREET, Suite 3120
	)	San Diego, CA 92101

APPEAL BRIEF

Commissioner of Patents and Trademarks
Washington, DC 20231

Dear Sir:

This brief is submitted under 35 U.S.C. §134 and is in accordance with 37 C.F.R. Parts 1, 5, 10, 11, and 41, effective September 13, 2004 and published at 69 Fed. Reg. 155 (August 2004). This brief is further to Appellant's Notice of Appeal filed herewith.

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(1) Real Party in Interest

The real party in interest is Alsius Corp.

(2) Related Appeals/Interferences

No other appeals or interferences exist which relate to the present application or appeal.

(3) Status of Claims

Claims 5-8 and 22-34 are pending and finally rejected, Claim 38 (referred to by the Examiner as Claim 39) has been restricted out, and the remaining claims have been cancelled.

(4) Status of Amendments

No amendments are outstanding.

(5) Concise Explanation of Subject Matter in Each Independent Claim, with Page and Figure Nos.

As an initial matter, it is noted that according to the Patent Office, the concise explanations under this section are for Board convenience, and do not supersede what the claims actually state, 69 Fed. Reg. 155 (August 2004), see page 49976. Accordingly, nothing in this Section should be construed as an estoppel that limits the actual claim language.

Claim 5 recites a central venous line catheter (reference numeral 20, page 7, first paragraph of detailed description, Figure 1) having at least one substantially elongate structure (id. and page 8, second paragraph and Figures 2-5) configured for establishing central venous access. The structure has a proximal

portion and a distal portion and defines at least a first lumen (e.g., 32, Figures 3 and 4, page 10, first paragraph) in communication with the exterior of the elongate structure at said proximal and distal portions, and at least one heat exchange element (24, Figures 1-4, page 8 starting with last four lines) extending at least along the distal portion and adapted to effect heat exchange with the central venous system. The catheter is manufactured by flushing the first lumen from its distal portion to its proximal portion with sterile saline.

The page and figure references above are incorporated into this paragraph. In Claim 22, a venous line catheter system (10, figure 1, pages 7-8) has a catheter having at least one substantially elongate structure configured for establishing central venous access. The structure has a proximal portion and a distal portion and defines at least a first lumen in communication with the exterior of the elongate structure at said proximal and distal portions, and at least one heat exchange element extending at least along the distal portion adapted to effect heat exchange with the central venous system. Unlike the invention of Claim 5, in Claim 22 a pump (in the module 50, figure 1, page 12 at bottom) feeds a heating/cooling agent at a flow rate in a range of 150 – 450 milliliters per minute through the heat exchange element (original Claim 22).

(6) Grounds of Rejection to be Reviewed on Appeal

(a) Claims 5-8, 22-27, and 31-34 have been rejected under 35 U.S.C. §102 as being anticipated by Williams et al. (USPN 4,941,475).

(b) Claims 5-8 and 22-34 have been rejected under 35 U.S.C. §102 as being anticipated by Bresnaham et al. (USPN 6,117,105).

(7) Argument

As an initial matter, it is noted that according to the Patent Office, a new ground of rejection in an examiner's answer should be "rare", and should be levied only in response to such things as newly presented arguments by Applicant or to address a claim that the examiner previously failed to address, 69 Fed. Reg. 155 (August 2004), see, e.g., pages 49963 and 49980. Furthermore, a new ground of rejection must be approved by the Technology Center Director or designee and in any case must come accompanied with the initials of the conferees of the appeal conference, id., page 49979. The same philosophy would seem to hold true for reopening prosecution after an appeal brief is filed.

Accordingly, it is noted that no new arguments are advanced below that have not already been made to the examiner. It is further noted that the examiner has now twice had the opportunity to address the flow rate limitation of Claim 22, and has failed to do so, meaning that reopening prosecution now under the guise of "addressing a claim not previously addressed" would be improper, since Claim 22 has been addressed, if haphazardly, multiple times. Accordingly, under the belief that the Patent Office, as a government agency, really ought to stay true to its word to the public, prosecution should not be reopened nor should any new ground of rejection be entered in an Answer. Consequently, this application should be allowed or be passed to the Board.

Claims 5-8, 22-27, and 31-34 have been rejected under 35 U.S.C. §102 as being anticipated by Williams et al., USPN 4,941,475, and Bresnaham et al., USPN 6,117,105. It is noted that the citation to the "entire reference" for each of the above-mentioned references in support of the rejections renders analysis of what the examiner is thinking problematic, and in any case is contrary to the guidance of MPEP §706.02(j)

(the Examiner should set forth (1) the relevant teachings of the prior art relied upon, preferably with reference to the relevant column or page number(s) and line number(s) where appropriate...)

The allegation that Williams et al. is a "venous line catheter" is contrary to MPEP §2111.01 (terms must be construed as the skilled artisan construes them), because Williams et al. is placed in the heart to measure cardiac output, and no evidence exists of record that the skilled artisan regards heart-dwelling cardiac output measuring catheters as "venous lines". This observation has elicited the retort that "any catheter has the ability to be used as a venous catheter". In and of itself, that response merits reversal. It is facially wrong. Any catheter CANNOT be used as central venous line catheter, nor would the skilled artisan (a doctor) confuse a cardiac output catheter such as the one disclosed in Williams et al. (which, when positioned, must have its operative portion in the arterial system, not the venous system, in order to work) with a central line. It is legal error to impute such faulty education in catheter types to the skilled artisan.

Furthermore, the rejections of Claim 5 are contrary to MPEP §2131 and consequently must be withdrawn because they fail to mention the limitation of Claim 5 that the catheter is manufactured by flushing the first lumen from its distal portion to its proximal portion with sterile saline. This is a structural limitation, since it means that residual salt remains in the lumen. This has been met with the argument that "applicant is reading limitations from the specification into the claims", because "there is no limitation that describes salt being left on the catheter".

It should be noted that Appellant is not here relying on a bare product-by-process limitation. Rather, anything flushed with salt cannot help but have at least some amount of residual salt on it, whether residual salt is claimed or not. In effect, the product-by-process limitation cannot but require a structure - a catheter with residual salt in a lumen - that is not present in the relied-upon references.

The filing date (December 4, 1998) of Bresnaham et al. is after the earliest claimed priority date of the present application. It has not been shown that Bresnaham et al. is entitled to the filing date of the provisional from which it claims priority, and MPEP §2136.03(III) (May, 2004 revision) grants a reference the date of an underlying provisional only insofar as the provisional discloses the relied-upon subject matter. Since the Bresnaham et al. provisional application has not been introduced into evidence and since no allegation has been made that the present application is not entitled to its earliest claimed priority date, the rejections based on Bresnaham et al. have been overcome.

This observation has been countered with a bare allegation that "applicant must overcome the filing date of the provisional". No, not under the new version of the MPEP, which has apparently escaped the examiner's attention. Unless it can be shown ***by the examiner, who is seeking to introduce the reference into evidence***, that the underlying provisional application supports the relied-upon subject matter, under Patent Office rules the rejection falls.

The rejections of Claim 22 are contrary to MPEP §2131 because they fail to mention the flow rate range limitation of Claim 22, and consequently must be withdrawn. This limitation continues to be ignored.

To date, no mention has been made of the dependent claims, much less has it been identified where their respective limitations appear in the relied-upon references despite repeated chances on the part of the examiner to do so. Having forced the present appeal after issuing multiple rejections, it would be exasperating and unacceptable indeed to cascade prosecution costs by reopening prosecution or otherwise contesting the patentability of these claims.

Respectfully submitted,

John L. Rogitz
Registration No. 33,549
Attorney of Record
750 B Street, Suite 3120
San Diego, CA 92101
Telephone: (619) 338-8075

JLR:jg

APPENDIX A

5. A central venous line catheter, said catheter having at least one substantially elongate structure configured for establishing central venous access, said structure having a proximal portion and a distal portion and defining at least a first lumen in communication with the exterior of the elongate structure at said proximal and distal portions, and at least one heat exchange element extending at least along the distal portion adapted to effect heat exchange with the central venous system, characterized in that the catheter is manufactured by flushing the first lumen from its distal portion to its proximal portion with sterile saline.

6. The catheter of claim 5, characterized in that the volume of the flushing sterile saline is at least 5 ccm.

7. The catheter of claim 6, characterized in that a 5 ccm or larger syringe is used for flushing.

8. The catheter of claim 6, characterized in that injection caps are clamped to the proximal portion of the first lumen.

22. A venous line catheter system, said system having a catheter having at least one substantially elongate structure configured for establishing central venous access, said structure having a proximal portion and a distal portion and defining at least a first lumen in communication with the exterior of the elongate structure at said proximal and distal portions, and at least one heat exchange element extending at least along the distal portion adapted to effect heat exchange with the central venous system, characterized by a pump feeding heating/cooling agent at a flow rate in a range of 150 - 450 milliliters per minute through the heat exchange element.

23. The catheter system of claim 22, characterized in that the flow rate is about 240 milliliters per minute.

24. The catheter system of claim 22, characterized in that the temperature of the heating agent is between 38°C and 43°C.

25. The catheter system of claim 22, characterized in that the temperature of the cooling agent is between 1°C and 5°C.

26. The catheter system of claim 22, characterized in that the heat exchanging element is a balloon.

27. The catheter system of claim 26, characterized in that the balloon length is about 55-60 mm.

28. The catheter system of claim 22, characterized in that the heat exchanging element comprises a plurality of balloons.

29. The catheter system of claim 28, characterized in that the balloon length is about 55-60 mm.

30. The catheter system of claim 28, characterized in that three balloons are disposed in a consecutive order, a first balloon having a diameter of approximately 8-12 mm, a second balloon having a diameter of approximately 5-9 mm, and a third balloon having a diameter of approximately 4-6 mm.

31. The catheter system of claim 26, characterized in that the wall thickness of the balloon is between 35 μm and 70 μm.

32. The catheter system of claim 22, characterized in that the material from which the balloon is made is selected from the group: urethane, nylon, PE and PET.

33. The catheter system of claim 22, characterized in that the heat conductivity of the balloon is 0.1 to 1.5 Watt per meter x Kelvin.

34. The catheter system of claim 22, characterized in that the heating/cooling agent is a sterile saline.

APPENDIX B - EVIDENCE

None (this sheet made necessary by 69 Fed. Reg. 155 (August 2004), page 49978.)

APPENDIX C - RELATED PROCEEDINGS

None (this sheet made necessary by 69 Fed. Reg. 155 (August 2004), page 49978.)